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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

CMS-4131-F2

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Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs:

Negotiated Pricing and Remaining Revisions; Prescription Drug Benefit Program:

Payments to Sponsors of Retiree Prescription Drug Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements and finalizes provisions regarding the reporting of gross covered retiree plan-related prescription drug costs (gross retiree costs) and retained rebates by Retiree Drug Subsidy (RDS) sponsors; and the scope of our waiver authority under the Social Security Act (the Act).

EFFECTIVE DATE: These regulations are effective on [OFR: insert date 60 days after the date of publication in the **Federal Register**].

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SUPPLEMENTARY INFORMATION:**I. Background**

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) that established the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived.

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) was enacted on December 8, 2003. This legislation established the Medicare prescription drug benefit program (Part D) and made significant revisions to the provisions in Medicare Part C, governing what was renamed the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program. The MMA also created a subsidy program involving payments to sponsors of Retiree Prescription Drug Programs, or the Retiree Drug Subsidy (RDS) Program. This program allows subsidy payments to sponsors of qualified retiree prescription drug plans for Part D drug costs for individuals who are eligible for, but not enrolled in, a Medicare Part D plan. The MMA also specified that implementation of the prescription drug benefit and revised MA program provisions take place by January 1, 2006. Thus, we published final

rules for the MA and Part D prescription drug programs in the January 28, 2005 **Federal Register** (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

We published a proposed rule on May 16, 2008 (73 FR28556) that proposed to make the Part D and RDS policies the same with respect to the reporting of negotiated prices and retained rebates. The May 2008 proposed rule would have required that Prescription Drug Benefit Program (Part D) and Retiree Drug Subsidy (RDS) sponsors report the pass-through negotiated prices and included a proposed definition of "negotiated price" to be included at §423.882 that paralleled the definition at §423.100. The May 2008 proposed rule also proposed to include definitions of "actually paid," "administrative costs," "allowable retiree costs," and "gross covered retiree plan-related prescription drug costs" that reflected Part D policy on retained rebates and "pass-through" negotiated prices, and proposed to apply the policies to the RDS Program. Thus, our proposed rule would have also required RDS sponsors to report rebates retained by an intermediary contracting organization, such as a pharmacy benefit manager (PBM), that may have been received by an intermediary contracting organization based on the utilization by the RDS sponsor's enrollees, but not passed through to the plan sponsor.

In the January 12, 2009 **Federal Register** (74 FR 1494), we published a final rule with comment period that responded to comments on the May 16, 2008 proposed rule and finalized Part C and Part D regulations from that proposed rule that either were not impacted by Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), which was enacted on July 15, 2008, or that complemented MIPPA

provisions. In addition, the final rule with comment period -- (1) deferred finalizing the RDS definition of "negotiated prices" and implemented, on an interim final basis, definitions of the other terms that reflected existing RDS policy, but did not reflect the new Part D policy on negotiated prices and retained rebates; (2) solicited public comment on whether we have the authority to adopt different reporting structures for Part D versus the RDS Program; and (3) set forth three theories under which we might have such authority.

Also in the January 12, 2009 **Federal Register**, we published a proposed rule that would make regulatory revisions based on a change in our interpretation of section 1860D-22(b) of the Act. This provision would be interpreted as providing us with the authority to waive or modify requirements that hinder the design of, the offering of, or enrollment in an RDS plan.

II. Provisions of the Rules and Analysis and Response to Public Comments

Based on comments on the May 2008 proposed rule, in our January 12, 2009 final rule with comment period (74 FR 1494), we deferred finalizing the definition of "negotiated prices" and implemented, on an interim final basis, definitions of the other terms that reflected existing RDS policy, but did not reflect the new Part D policy on negotiated prices and retained rebates. Stakeholders that commented on the May 2008 proposed rule argued that the majority RDS sponsors are large employers that are sophisticated purchasers with a great amount of leverage, and are in the best negotiating position to decide which pricing structure is most appropriate for them. Commenters on the May 2008 proposed rule also argued that to extend the Part D policy of requiring the

reporting of pass-through prices (and retained rebates) would cause RDS sponsors to leave the program and place retirees in the Medicare Part D program.

We also at that time requested comment on whether we have the authority to adopt different reporting structures for Part D versus the RDS Program, and our final rule with comment period set forth three theories under which we might have such authority. These legal theories are described in detail in our January 12, 2009 final rule with comment period (74 FR 1494, 74 FR 1516, and 74 FR 1519). Although the three legal theories were articulated in connection with our decision to defer finalizing the proposed definition of "negotiated prices" in the RDS regulations (which would have tracked the Part D definition at §423.100), we also stated in the January 12, 2009 final rule with comment that we believed these three legal theories also could have applicability to the issue of whether we could adopt a policy for retained rebates that differed between RDS and Part D, and we sought comment on that issue as well.

A. Provisions of the Final Rule with Comment Period

In January 12, 2009 **Federal Register** (74 FR 1494), we published a final rule with comment period that finalized certain requirements relating to the MA and Part D Programs, and implemented certain requirements for the RDS Program on an interim basis. In the preamble discussion of these interim final regulations, we indicated that we agree with concerns expressed by commenters regarding the application to the RDS program of two Part D policies that were being finalized. We also indicated that the interim final regulations preserve the status quo for the RDS program with respect to these policies while we invited comment on three different legal theories under which we

could potentially apply different cost reporting structures between the Part D and RDS Programs. That is, under Part D, sponsors are required to report pass-through pricing and retained rebates, but under the RDS Program, sponsors would be permitted to choose whether or not to report drug costs on a pass-through or lock-in basis, and could choose to report rebates and other price concessions that are retained by a pharmacy benefit management company or other intermediary contracting organization. In addition, the January 2009 proposed rule noted that we were specifically soliciting comments on the possibility of applying one or more of these legal theories.

We received comments from 10 stakeholders on the final rule with comment period. Commenters included advocacy groups representing the insurance industry, and employers and other organizations that sponsor or administer retirement and health benefits; pharmacy benefit managers; a health care consortium; and a consultant.

Commenters generally supported allowing the RDS Program reporting structure to be different from the Part D reporting structure, and commenters generally believed that we have the authority to allow differing reporting structures. In this final rule, based on the comments received both on the interim final portions of the January 12, 2009 final rule with comment, as well as comments received on the proposed rule published the same day, we are finalizing the RDS language as specified in the January 2009 final rule with comment period (73 FR 1494) (with the correction discussed in section II.C. of this final rule), and the proposed regulatory changes for part 423 subpart J in the January 2009 proposed rule (74 FR 1550). Therefore we are finalizing the definitions of "actually paid," "administrative costs," "allowable retiree costs," "gross covered retiree

plan-related prescription drug costs, or gross retiree costs," as they were published in the January 12, 2009 final rule with comment period. We are also finalizing the revision of §423.888(b)(5)(i) so that it references the term "gross covered plan-related retiree prescription drug costs," which is a term defined in part 423 subpart R, rather than "gross prescription drug costs," which is not. Finally, we are making the one technical change to the definition of "actually paid" to make clear that direct and indirect remuneration can be from any source, as opposed to only from manufacturers or pharmacies. (We are also finalizing the regulatory waiver language set out in §423.458(c) as proposed on the same day in the January 2009 proposed rule, as discussed in this section.)

While we believe the Part D and RDS Programs are mutually exclusive programs, both are established under Part D-Voluntary Prescription Drug Benefit Program, and implemented under 42 CFR Part 423. Therefore, we believe it is best to interpret parallel statutory language in the same manner, but use waiver authority to waive RDS requirements that, if interpreted consistently with parallel Part D requirements, would hinder the offering of, design of, or enrollment in, RDS plans.

1. Legal Theory 1: Interpretation of "Actually Paid"

In our January 12, 2009 final rule with comment period (74 FR 1516), we articulated our first of three legal theories that would authorize us to adopt a different reporting policy for RDS than for Part D. Under this theory, when an RDS sponsor makes a payment to an entity (such as a PBM) that includes amounts for Part D drug ingredient and dispensing costs and amounts to manage the sponsor's drug benefit plan, the amount of that payment represents the "costs that are actually paid by the sponsor" for

purposes of calculating the subsidy. Under this argument, we would calculate the subsidy payment based on the RDS sponsor's payment to the PBM, excluding discounts, chargebacks, and average percentage rebates. A problem with this theory is that it would arguably read out of the statute the phrase "for the portion of the retiree's gross covered retiree plan-related prescription drug costs" because the amount actually paid could include administrative costs.

Comment: Several commenters indicated that they view the Part D and RDS programs as mutually exclusive programs and that, as a result, we could interpret statutory provisions governing the two programs differently, even if the statutory language in the two provisions were the same. One commenter stated that based on Congressional intent it did not believe policy changes in Part D need to be in lockstep with other programs. One commenter specifically pointed out that the term "administrative costs" does not have to be interpreted in the same manner between the Part D and RDS Programs. Another commenter indicated that, in light of fact that section 1860D-22 of the Act is titled "Special Rules for Employer-Sponsored Programs," the MMA intended special treatment for retiree plans compared to Part D Plans.

Response: We agree that the Part D program and the RDS program are different programs with different purposes, and as such, merit different treatment when appropriate to serve those different purposes. We also agree that the heading for section 1860D-22 of the Act implies that the RDS program merits special treatment. That said, we also believe that because the relevant provision uses the same statutory language in both programs to describe program costs, we should interpret the language consistently.

Given these considerations, as described in further detail later in this section, we will use our waiver authority under section 1860D-22(b) of the Act to waive or modify the RDS statutory requirements that would otherwise require that RDS sponsors report costs in the same manner as Part D sponsors.

Comment: A commenter contended that the RDS sponsor incurs integrated costs that are directly related to the drug benefit management services necessary for the plan's operation and therefore they should be considered costs "actually paid." Another commenter believes that the "actually paid" theory is not very strong because it reads out of the statute the prohibition on including administrative costs when determining a retiree's "allowable retiree costs." Another commenter believed that if CMS views costs a sponsor pays to a PBM under lock-in as "drug costs incurred to purchase or reimburse the purchase of Part D drugs," and not as administrative costs, the prohibition on including administrative costs would not be read out of the statute. One commenter stated that the same term can be interpreted differently for different programs and that courts give deference to an agency's reasonable interpretation of a statutory term. Another commenter believes that "actually paid" means the lock-in price rather than the pass-through price.

Response: We appreciate the comments on this issue. Based on the totality of the comments on our final rule with comment and proposed rule, however, we have determined that the best approach is to adopt legal theory 3, discussed in further detail below. Such an approach will permit us to impose reporting requirements on RDS sponsors that diverge from those under Part D without having to interpret parallel

language in two different sections of the Part D statute (namely, sections 1860D-15 and 1860D-22 of the Act) inconsistently. Under the approach we are adopting, when an RDS sponsor makes a payment to an entity (such as a PBM) that includes amounts for Part D ingredient and dispensing costs and amounts to manage the sponsor's drug benefit plan, the total amount of the payment can be used for purposes of calculating the subsidy; otherwise referred to as "lock-in" pricing. This lock-in amount paid will be sufficient for us to calculate the subsidy payment, excluding discounts, chargebacks, and average percentage rebates. Under this approach, RDS sponsors can choose to report either the lock-in or the pass-through price for reporting drug costs for purposes of subsidy payments (and can choose to report retained rebates).

Comment: One commenter supported applying the Part D negotiated price definition to the RDS Program, but asked that adequate time be allowed to implement the changes needed to report costs based on pass-through, because the terms of its contracts with PBMs, and, in turn, the PBMs' contracts with pharmacies and other providers, may need to be changed to accommodate the new reporting requirements. Most other commenters supported the existing RDS negotiated price policy, which allows an RDS sponsor to report either the lock-in or pass-through price, because it will promote continued participation of employers.

Response: For the reasons described later in this preamble, we are not adopting a definition of negotiated prices for the RDS program. Thus, the Part D policy with respect to the use of pass-through negotiated prices does not apply to the RDS program.

2. Legal Theory 2: Prohibition on Interference With Benefit Design of Retiree Drug Coverage

The second legal theory on which we invited public comment was the theory that the RDS statute prohibits CMS from interfering in the benefit design of retiree drug coverage, and that requiring use of the "pass-through" methodology to report drug costs would interfere with the benefit design of qualified retiree prescription drug plans.

Section 1860D-22(a)(6)(D) of the Act provides that nothing in the RDS statute shall be construed as "preventing employers to provide for flexibility in benefit design so long as the actuarial equivalence requirement is met." Under this legal theory, requiring reporting of the pass-through price (and retained rebates) would be administratively burdensome, create an incentive for employers to redesign their RDS plans and their contractual arrangements with PBMs, and perhaps encourage employers to opt out of the RDS Program entirely.

This argument rests on the assumption that--(1) contractual arrangements between an RDS sponsor and a PBM are "benefit design[s]"; and (2) requiring an RDS sponsor to report the pass-through price for purposes of the subsidy would "prevent" employers from providing flexibility in those benefit designs. Arguably, section 1860D-22(a)(6)(D) of the Act is most reasonably interpreted to prohibit us from mandating a certain benefit package in retiree drug plans, and not to prohibit us from imposing requirements that relate only to reporting costs to us. The provision's context suggests that Congress was concerned with the benefit design of a retiree drug plan itself, and not with the relationship between an RDS sponsor and its contractors.

Comment: We received several comments in favor of our adopting legal theory 2. Several commenters noted that imposing Part D reporting requirements on the RDS program would reduce sponsors' flexibility in plan design, either directly or as a result of having to undertake contract modifications. One commenter stated that to require the Part D reporting structure for the RDS Program would alter the underpinnings of employer plan operations and result in RDS sponsors' modifying their plan benefits, because cost assumptions for prescriptions filled at a pharmacy would no longer be fixed. The commenter stated its belief that this cost variability, in turn, would likely result in changes in cost-sharing and could constrain RDS sponsors' flexibility in benefit design. Other commenters believe that requiring reporting of pass-through prices would discourage RDS sponsors from offering retiree drug coverage, which would push these retirees into Part D. Commenters also stated that requiring pass-through reporting would require considerable retooling of information systems.

Response: We appreciate the comments about the effect of the Part D reporting requirements on RDS sponsors. Based on the comments, we agree that imposing the Part D reporting requirements on RDS sponsors could constrain plan flexibility and ultimately reduce the number of RDS plans available to Part D eligible individuals. In other words, these requirements could hinder the offering of, design of, or enrollment in such plans. Although we are not foreclosing the possibility that we could interpret section 1860D-22(a)(6) of the Act in the manner described in our final rule with comment, we do not believe, given our decision to adopt legal theory 3, that it is necessary to adopt legal theory 2 at this time. Thus, using our waiver authority under 1860D-22(b) of the Act, we

will allow an RDS sponsor to report either the lock-in or pass-through prices (and to choose whether or not to report retained rebates). We believe this is the most prudent approach because it will help keep Part D eligible individuals in health plans with which they are satisfied.

3. Legal Theory 3: Change in Interpretation of Waiver Authority

The third legal theory on which we invited public comment involved a change in our interpretation of waiver authority in section 1860D-22(b) of the Act, and the use of that authority to modify requirements for RDS sponsors. The waiver authority in section 1860D-22(b) of the Act appears in a section of the Act that is otherwise devoted entirely to provisions that apply to the RDS Program. It provides that employer group waiver provisions in section 1857(i) of the Act (Medicare Part C) apply with respect to "prescription drug plans in relation to employment based retiree health coverage" in a manner similar to how they apply to employment-based MA plans. Under ordinary principles of statutory construction, when a term is defined in statute, the definition applies when the same statute employs that term. Thus, the plainest reading of the waiver authority in section 1860D-22(b) of the Act is that it applies only to prescription drug plans (PDPs), and not to qualified retiree prescription drug plans (QRPDP). However, given the fact that this waiver authority appears in a section otherwise devoted to the RDS program, and that the term "qualified retiree prescription drug plan" includes the three words, "prescription drug plan," we believed an argument might be made in this case that the term "prescription drug plan" was intended to encompass both a Part D "prescription drug plan" and a qualified retiree "prescription drug plan" (that is, this

waiver authority extends both to PDPs and QRPDPs), as long as the plan is offered "in relation to employment-based retiree health coverage" in either case. In the January 12, 2009 proposed rule, we proposed to change the regulations in Subpart J that interpret the waiver authority as applying only to Part D PDPs.

Comment: Some commenters believe that use of the waiver authority is the strongest theory upon which to rely for purposes of permitting diverging reporting requirements in RDS and Part D. Several commenters agreed that the term "qualified retiree prescription drug plan" includes the words "prescription drug plan," and therefore the waiver authority applies to RDS sponsors as long as a plan is offered "in relation to employment based retiree health coverage." Several commenters stated that we have the authority to construe the waiver authority to include RDS plans because even though the term "prescription drug plan" is defined to include only Part D plans, the phrase "prescription drug plans in relation to employment based retiree health coverage" is not, and commenters argue that this phrase could be construed to include RDS plans. Another commenter notes that the statutory definition of a qualified retiree prescription drug plan includes the term "employment-based retiree health coverage." Other commenters believe the term "prescription drug plan" can be interpreted differently when used in different contexts, even in the same statute, and that courts will give deference to how the agency defines or interprets a term.

Other commenters expressed concern that the use of the waiver authority to waive a Part D requirement that might hinder the RDS Program is inconsistent with the statutory construct of the waiver authority. One commenter notes that from a policy-

perspective, Part D plans are very different from RDS sponsors, and these differences made the commenter uncertain whether waiver authority designed for MA and Part D would apply to the RDS program because we do not have the same type of authority over RDS sponsors as we do over MA organizations and Part D plans.

Response: After consideration of these comments, we agree that we can construe the waiver authority in section 1860D-22(b) of the Act to apply to RDS plans if we read the phrase "prescription drug plans in relation to employment-based retiree coverage" as a whole, and interpret it to apply to RDS plans. Under this interpretation, we are authorized to waive requirements that hinder the design of, the offering of, or enrollment in RDS plans. We interpret the term "gross covered retiree plan-related prescription drug costs," as defined in section 1860D-22(a)(3)(C)(ii) of the Act, in a manner consistent with the term "gross prescription drug costs," as defined in section 1860D-15(b)(3) of the Act. That is, we believe that the same terminology used in these statutes must be interpreted the same way. Using waiver authority, however, we are waiving the prohibition on including administrative costs in the calculation of gross retiree costs (at §423.882 and §423.888) when an RDS sponsor pays an intermediary contracting organization on a lock-in basis to allow RDS reporting requirements that diverge from Part D requirements (see 74 FR 1549). In other words, we are waiving the requirement that "gross covered retiree plan-related prescription drug costs" exclude administrative costs because to require their exclusion from the costs RDS sponsors report to us – whether in the form of pass-through negotiated prices or reporting of retained rebates – would hinder the design of, the offering of, or enrollment in RDS plans. This waiver of

the prohibition on including administrative costs in the calculation of gross retiree costs will apply to costs paid on a lock-in basis (and the reporting of retained rebates) because we do not want to interfere with the contracting arrangements between an RDS sponsor and its intermediary contracting organization. Of course, an RDS sponsor may exclude administrative costs from the calculation of gross retiree costs, if it chooses to do so.

Therefore, we are not, as commenters suggest, using the waiver authority to waive Part D requirements; rather, we are using the waiver authority to waive RDS requirements that, if interpreted consistently with parallel language in the Part D statute, would require that we apply RDS reporting requirements that similarly parallel Part D requirements.

Regardless of whether an RDS sponsor chooses to report drug costs on a lock-in or pass-through basis, or whether the RDS sponsor reports retained rebates or not, for audit and other oversight purposes RDS sponsors must document the method of reporting drug costs and rebates, and produce the documentation in accordance with §423.888.

It is important to note that, with this authority, we are waiving only the prohibition on including administrative costs in the calculation of RDS payments, and only to the extent that such costs are included in the payment to the PBM or other intermediate contracting entity, whether as "lock in" prices or retained rebates. If RDS sponsors include in their contracts with intermediary contracting organizations specific administrative payments for specific administrative services, such payments could not be included in the calculation of RDS payments. We are not waiving any other RDS requirements, nor are we adopting any waivers for the RDS Program that exist relating to

the EGHP Program. The converse is also true; we are not applying waivers for the RDS program to the EGHP program.

If, in the future, we believe that we may need to waive another RDS requirement, we will post a proposal on the RDS public website with information on how stakeholders can comment on the proposal, and will allow sufficient time for stakeholders to comment.

Comment: Commenters noted that the definition of "gross covered prescription drug costs" is not defined in the RDS statute and that the definition under the Part D statute is limited to Part D.

Response: We believe the commenter is referring to the statutory definition of "allowable retiree costs" in section 1860D-22(b)(3)(C)(i) of the Act, which uses the term "gross covered prescription drug costs," instead of the term "gross covered retiree plan-related prescription drug costs." We do not believe this distinction is meaningful in light of section 1860D-22(a)(3) of the Act, which includes the term "gross covered prescription drug costs," but cross-references the definition of "gross covered retiree plan-related prescription drug costs" at section 1860D-22(b)(3)(C)(ii) of the Act. However, even if the distinction were meaningful, both terms exclude administrative costs when calculating allowable costs, so this prohibition must be waived for purposes of the regulations we are finalizing in this final rule.

Comment: A commenter argues that if rebates are retained by the PBM then they are not part of the cost of drugs for the RDS sponsor. If such rebates are part of the RDS sponsor's PBM contract they will change the cost paid by the plan and should be reported.

Response: Under the approach we are adopting for the RDS Program with respect to retained rebates, RDS sponsors are not required to report rebates that are retained by the PBM – we are waiving the requirement that such retained rebates be considered administrative costs that must be excluded from gross covered retiree plan-related prescription drug costs. Of course, if an RDS sponsor chooses to report the retained rebates, the subsidy payment will be adjusted accordingly.

B. Provisions of the Proposed Rule

In the January 12, 2009 **Federal Register** (74 FR 1550), we published a proposed rule that would amend the regulations pertaining to our waiver authority under section 1860D-22(b) of the Act to broaden our interpretation of the waiver authority. The proposed rule would permit the waiver of requirements that hinder the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan. In addition, the January 2009 proposed rule (74 FR 1551) noted that we were specifically soliciting comments on the possibility of applying one or more of those legal theories.

One of the legal theories discussed in the interim final rule with comment involves interpreting the waiver authority under section 1860D-22(b) of the Act (which incorporates waiver authority under section 1857(i) of the Act) to authorize us to waive requirements of the RDS statute to permit differences between the RDS and Part D programs with respect to the two policies in question. In our current regulations, however, we have interpreted section 1860D-22(b) of the Act to apply only to Medicare Part D plans, and not RDS plan sponsors. In order for us to change our interpretation of the scope of our waiver authority, therefore, we proposed to revise the regulations to

specify that the waiver authority applies to the RDS program.

Thus, to enable us potentially to adopt this legal theory, we published the January 2009 proposed rule to invite public comment on this proposed change. We also noted that after we have reviewed the comments received on the proposed rule and the RDS interim final regulations, we would determine whether to adopt any of the legal theories discussed in the preamble discussion of the RDS interim final rule, and whether to finalize the regulatory revisions based on our change in interpretation of section 1860D-22(b) of the Act set forth in the proposed rule.

We received seven timely comments from stakeholders on the January 12, 2009 proposed rule. Because the provisions of the January 2009 proposed rule are closely related to the legal theory provisions of the final rule with comment period, we responded to the comments regarding these provisions in section II.A. of this final rule.

After review of the comments, we are finalizing our proposed changes to part 423, Subpart J to reflect the proposed interpretation of our authority under section 1860D-22(b) of the Act. In addition, we are finalizing the regulations for the RDS program as set forth in the final rule with comment period. Specifically, we are declining to adopt the Part D definition of "negotiated price," we are not revising the definition of "actually paid" to require RDS sponsors to report retained rebates, and we are finalizing the other definitions set forth in §423.882 and the provisions of §423.888, as set forth in the final rule with comment period, subject to the modification described in section II.C. of this final rule.

C. Technical Correction

During our review of the comments on these rules, we noticed an inconsistency between the preamble discussions and the regulatory text in the May 2008 proposed rule; and the regulations text of the January 2009 final rule with comment period regarding the definition of the RDS term "actually paid".

Specifically, the preamble discussions of the RDS term "actually paid" in the May 2008 and January 2009 proposed rule and final rule with comment period, and the regulations text of the May 2008 proposed rule (73 FR 28571, 73 FR 28602, and 74 FR 1515, respectively), all note that direct and indirect remuneration can be from any source, and such remuneration will cause the amounts that are actually paid to be reduced. The regulatory text in the January 2009 final rule with comment period incorrectly specified that the direct and indirect remuneration may only be from any manufacturer or pharmacy.

The statutory definition of "allowable retiree costs", when stating that such costs are costs that are actually paid (net of discounts, chargebacks, and average percentage rebates), does not limit the source from which these discounts, chargebacks, and average percentage rebates come (see section 1860D-22(a)(3)(C)) of the Act (42 U.S.C. 1395w-132(a)(3)(C)). Limiting the source from which direct and indirect remuneration may be derived is not consistent with the proposed rule, or the preamble discussion in the interim final rule (nor is it consistent with the Part D regulations).

Therefore, in this final rule, we are making a technical correction to the definition of the RDS definition of "actually paid" (see §423.882) by revising the phrase "from any manufacturer or pharmacy" to read "from any source" because it does not matter from

what source direct or indirect remuneration comes, as long as the remuneration serves to decrease the costs incurred under the qualified retiree prescription drug plan. So the definition in §423.882 will read as follows:

Actually paid means, that the costs must be actually incurred by the qualified retiree prescription drug plan and must be net of any direct or indirect remuneration (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source that would serve to decrease the costs incurred under the qualified retiree prescription drug plan.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions of the January 2009 proposed rule and the provisions of the final rule with comment period (see section II.B.3. of this final rule) with the technical correction to §423.882 described in section II.C. of this final rule.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security

Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule is not a significant and/or an economically significant rule. This rule will not impose added benefits or costs on stakeholders because it allows stakeholders the same reporting flexibilities that they exercise currently.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that this rule will not have a significant impact on a substantial number of small entities. In fact, the policy approach taken in this final rule is intended to minimize impacts on any size business, including small businesses, or other small entities. This final rule allows RDS sponsors the flexibility to report drug costs on either a pass-through or lock-in basis, so that they may negotiate arrangements most beneficial to the RDS sponsor, and allows RDS sponsors to choose whether they will report retained rebates. This rule does not affect hospitals or other health care providers because the rule relates to how an RDS sponsor reports drug costs in order to receive an

RDS payment. The amounts reported do not relate to the amounts actually paid to hospitals and other providers because the subsidy is an after-the-fact subsidy; meaning that the drug costs are incurred and paid and then an RDS sponsor may receive an RDS payment. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals, because it does not relate to small rural hospitals either directly or indirectly. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of \$136 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State

and local governments, preempts State law, or otherwise has Federalism implications.

This rule will not have a substantial direct effect on State or local governments, nor will it preempt States, or otherwise have a Federalism implication.

B. Anticipated Effects

We do not anticipate effects on RDS sponsors, other providers or the Medicare program.

C. Alternatives Considered

We considered requiring RDS sponsors to report pass-through pricing and to require the reporting of retained rebates but decided against this approach because commenters believe that requiring these reporting structures could cause RDS sponsors not to participate in the RDS Program.

D. Conclusion

We do not believe that this rule will have an impact on RDS sponsors or any other stakeholders. We do not believe that a regulatory flexibility analysis, or an analysis required by section 1102(b) of the Act, are required, beyond the analysis performed in this section and the discussions provided in the section II. of this final rule.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 423 as set forth below:

PART 423- VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w-101 through 1395w-152, and 1395hh).

Subpart J--Coordination of Part D Plans with Other Prescription Drug Coverage

2. Section 423.454 is amended by revising the definition "Employer-sponsored group prescription drug plan" to read as follows:

§423.454 Definitions.

* * * * *

Employer-sponsored group prescription drug plan means, prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage. For purposes of this subpart, employment-based retiree health coverage is such coverage (as defined in § 423.882) provided through a Medicare Part D plan, or for which a plan sponsor could qualify for payments under Subpart R of this part.

* * * * *

3. Section 423.458 is amended as follows:
 - A. Republishing the heading of paragraph (c).
 - B. Revising paragraph (c)(1).
 - B. Redesignating paragraph (c)(2) as paragraph (c)(3).
 - D. Adding a new paragraph (c)(2).

The revision and addition read as follows:

§423.458 Application of Part D rules to certain Part D plans on and after January 1, 2006.

* * * * *

(c) Employer group waiver—(1) General rule for employer-sponsored group prescription drug plans that are Medicare Part D plans. CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan, including authorizing the establishment of separate premium amounts for enrollees of the employer-sponsored group prescription drug plan and limitations on enrollment in such plan to Part D eligible individuals participating in the sponsor's employment-based retiree health coverage. Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

(2) General rule for employer-sponsored group prescription drug plans for which a sponsor could qualify for payments under Subpart R of this part. CMS may waive or modify any requirement under this part that hinders the design of, the offering of, or the enrollment in an employer-sponsored group prescription drug plan.

* * * * *

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

§423.882 [Amended]

4. In §423.882, the definition of "Actually paid" is amended by removing the phrase "manufacturer or pharmacy" and adding the term "source" in its place.

CMS-4131-F2

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: November 3, 2011

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: January 6, 2012

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

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